(6) Smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

(b) No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under section 502(b) of the act, shall apply if such insufficiency is caused by:

(1) The use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(2) The use of label space to give greater conspicuousness to any word, statement, or other information than is required by section 502(c) of the act; or

(3) The use of label space for any representation in a foreign language.

(c)(1) All words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language: *Provided, however*, That in the case of articles distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language may be substituted for English.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language.

(3) If the labeling contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear on the labeling in the foreign language.

§ 801.16 Medical devices; Spanish-language version of certain required statements.

If devices restricted to prescription use only are labeled solely in Spanish for distribution in the Commonwealth of Puerto Rico where Spanish is the predominant language, such labeling is authorized under § 801.15(c).

§ 801.18 Format of dates provided on a medical device label.

(a) *In general.* Whenever the label of a medical device includes a printed expiration date, date of manufacture, or any other date intended to be brought to the attention of the user of the device, the date must be presented in the following format: The year, using four digits; followed by the month, using two digits; followed by the day, using two digits; each separated by hyphens. For example, January 2, 2014, must be presented as 2014–01–02.

(b) *Exceptions.* (1) A combination product that properly bears a National Drug Code (NDC) number is not subject to the requirements of paragraph (a) of this section.

(2) If the device is an electronic product to which a standard is applicable under subchapter J of this chapter, Radiological Health, the date of manufacture shall be presented as required by § 1010.3(a)(2)(ii) of this chapter.

[78 FR 58818, Sept. 24, 2013]

Subpart B—Labeling Requirements for Unique Device Identification

§ 801.20 Label to bear a unique device identifier.

(a) *In general.* (1) The label of every medical device shall bear a unique device identifier (UDI) that meets the requirements of this subpart and part 830 of this chapter.

(2) Every device package shall bear a UDI that meets the requirements of this subpart and part 830 of this chapter.

(b) *Exceptions.* Exceptions to the general rule of paragraph (a) of this section are provided by §§ 801.30, 801.45, and 801.128(f)(2), and § 801.55 provides a means to request an exception or alternative not provided by those provisions.

[78 FR 58818, Sept. 24, 2013]

§ 801.30 General exceptions from the requirement for the label of a device to bear a unique device identifier.

(a) *In general.* The following types of devices are excepted from the requirement of § 801.20; a device within one or more of the following exceptions is not

required to bear a unique device identifier (UDI):

(1) A finished device manufactured and labeled prior to the compliance date established by FDA for § 801.20 regarding the device. This exception expires with regard to a particular device 3 years after the compliance date established by FDA for the device.

(2) A class I device that FDA has by regulation exempted from the good manufacturing practice requirements of part 820 of this chapter, exclusive of any continuing requirement for recordkeeping under §§ 820.180 and 820.198.

(3) Individual single-use devices, all of a single version or model, that are distributed together in a single device package, intended to be stored in that device package until removed for use, and which are not intended for individual commercial distribution. This exception is not available for any implantable device. The device package containing these individual devices is not excepted from the requirement of § 801.20, and must bear a UDI.

(4) A device used solely for research, teaching, or chemical analysis, and not intended for any clinical use.

(5) A custom device within the meaning of § 812.3(b) of this chapter.

(6) An investigational device within the meaning of part 812 of this chapter.

(7) A veterinary medical device not intended for use in the diagnosis of disease or other conditions in man, in the cure, mitigation, treatment, or prevention of disease in man, or intended to affect the structure or any function of the body of man.

(8) A device intended for export from the United States.

(9) A device held by the Strategic National Stockpile and granted an exception or alternative under § 801.128(f)(2).

(10) A device for which FDA has established a performance standard under section 514(b) of the Federal Food, Drug, and Cosmetic Act and has provided therein an exception from the requirement of § 801.20, or for which FDA has recognized all or part of a performance standard under section 514(c) of the Federal Food, Drug, and Cosmetic Act and has included an exception from the requirement of § 801.20 within the scope of that recognition.

(11) A device packaged within the immediate container of a combination product or convenience kit, *provided that* the label of the combination product or convenience kit bears a UDI.

(b) *National Drug Code (NDC) Numbers.* If a combination product properly bears an NDC number on its label—

(1) The combination product is not subject to the requirements of § 801.20.

(2) A device constituent of such a combination product whose components are physically, chemically, or otherwise combined or mixed and produced as a single entity as described by § 3.2(e)(1) of this chapter is not subject to the requirements of § 801.20.

(3) Each device constituent of such a combination product, other than one described by § 3.2(e)(1) of this chapter, must bear a UDI on its label unless paragraph (a)(11) of this section applies.

(c) *Exception for shipping containers.* This rule does not require a UDI to be placed on any shipping container.

(d) The UDI of a class I device is not required to include a production identifier.

[78 FR 58818, Sept. 24, 2013]

§ 801.35 Voluntary labeling of a device with a unique device identifier.

(a) The labeler of a device that is not required to bear a unique device identifier (UDI) may voluntarily comply with § 801.20. If a labeler voluntarily includes a UDI for a device, the labeler may voluntarily provide information concerning the device under subpart E of part 830 of this chapter.

(b) A device may bear both a Universal Product Code (UPC) and a UDI on its label and packages.

[78 FR 58818, Sept. 24, 2013]

§ 801.40 Form of a unique device identifier.

(a) Every unique device identifier (UDI) must meet the technical requirements of § 830.20 of this chapter. The UDI must be presented in two forms:

(1) Easily readable plain-text, and

(2) Automatic identification and data capture (AIDC) technology.

(b) The UDI must include a device identifier segment. Whenever a device label includes a lot or batch number, a